REMARKS / ARGUMENTS

Currently Pending Claims

Claims 47, 49, 50, 52 and 54-65 are pending. By the foregoing amendment, the applicants have amended claims 47 and 65 and canceled claims 48 and 68. Claim 69 is withdrawn. No new matter is added by the amendment. Support for the amendments can be found in the specification as filed. In view of the foregoing amendments and following discussion, the applicants submit that all pending claims are in condition for allowance.

Restriction

Applicant traverses the present restriction of claim 69 as well as the previous restriction of claims 66 and 67. Applicant contends that there is a common novel technical feature shared by the two inventive groups proposed by the examiner, that feature being a formulation comprising eicosapentaenoic acid or an ester thereof; and a triterpene or an ester thereof, wherein the formulation comprises less than about 0.1% docosahexaenoic acid. Applicant therefore requests rejoinder of claim 66-67 and 69.

Amendments to the claims

Claims 47 and 65 are amended to remove the limitation to a triterpene of "pure botanical".

Claims 48 and 68 are cancelled as not further limiting the claims from which they depend.

No new matter is added by the amendments to the claims.

Objections to claims 52 and 54-56

The objections are overcome by the amendment to claim 47, because claim 47 no longer requires a pure botanical triterpene, and therefore present claims 52 and 54-56 do not broaden the scope of present claim 47.

Rejection of claims 47-50, 52, 54-60 and 68 under 35 U.S.C. 112, first paragraph

The present rejections under this paragraph are made moot by the present amendment to claims 47 and 65 to remove the phrase "pure botanical". Therefore, no new matter is added in present claims 47-50, 52, 54-60 and 68.

Rejection of claims 47-50, 52, 54-60 and 68 under 35 U.S.C. 112, second paragraph

The present rejection under this paragraph concerning the phrase "pure botanical" is made moot by the present amendment to claims 47 and 65.

Rejection of claims 47-50, 52, 54-63, 65 and 68 under 35 U.S.C. 102(b)

The examiner has rejected claims 47-52, 54-63, 65 and 68 under 35 U.S.C. 102(b) as being anticipated by Horrobin et al. (US Patent 5,145,686) on the grounds that Horrobin does not disclose docosahexaenoic acid, nor does it disclose that the eicosapentaenoic acid in the disclosed compositions is in the form of fish oil, and that it is reasonable to conclude from Horrobin that docosahexaenoic acid is not present in the compositions.

Claims 48, 51 and 68 are cancelled and therefore the rejections of these claims are moot.

With regard to the remaining claims rejected under this statute, applicant respectfully contends that the examiner is concluding more than is warranted by Horrobin's disclosure of eicosapentaenoic acid in US Patent 5,145,686. Applicant respectfully disagrees that it can be concluded that the Horrobin compositions contain less than 0.1% docosahexaenoic acid. It would be known by those skilled in the art that eicosapentaenoic acid is not found independent of its immediate metabolite, docosahexaenoic acid, unless it is prepared in a form that has been purified of docosahexaenoic acid. Horrobin, in contemporaneous publications, confirms that DHA is a metabolite of EPA (see Horrobin et al., European Patent 0585026 at page 4, lines 19-20, enclosed; and Horrobin et al., European Patent EP 0347056 at page 2, enclosed). DHA is the immediate n-3 series metabolite of EPA and would naturally be present in EPA formulations that comprise normal EPA, a fact that would be known by Horrobin at the invention date of the '686 as well as by those skilled in the art at the time. Generally, the presence of DHA in EPA-containing compositions is considerably more than 1%.

The enclosed affidavit from Chemport Inc, an international Korea-based manufacturer of EPA (see http://chemport.en.ec21.com/GC00045640/CA00045641/Fatty_acid_ester.html) confirms the natural presence of DHA associated with EPA and the need to purify EPA to exclude the presence of even 1% DHA. Applicant's specification, on the other hand, discloses an exemplary method for obtaining purified EPA having less than 0.1% docosahexaenoic acid (see page 11, lines 11-13), but it would be known by the skilled person

that extraction of EPA from any source would require additional purification of EPA to substantially exclude DHA.

To prepare EPA comprising less than 0.1% DHA with the EPA, as is required in claim 47, therefore requires preparing EPA in a purified form, and the fact that the '686 does not disclose *adding DHA* does not alter the fact that DHA would naturally be present with EPA as its metabolite, unless the EPA is prepared in a purified form to exclude DHA. In the '686 patent, Horrobin makes no mention of purifying EPA to exclude DHA, and certainly does not disclose less than 0.1% DHA in the disclosed formulations. Therefore, applicant contends that the Horrobin compositions would naturally contain some DHA (at least 1%, and considerably more than less than 0.1%) because there is no mention or suggestion in the '686 of purifying the EPA, let alone purifying the EPA to exclude more than 0.1% DHA. Indeed, the only relevant disclosure is the use of either an n-3 series fatty acid (EPA) or an n-6 series fatty acid (dihomo-gamma-linoelic acid) (see the '686 at Table III), of which the n-3 series fatty acid (EPA) would most certainly contain its immediate metabolite DHA unless purified to exclude DHA.

Therefore, applicant contends that the Horrobin compositions do not anticipate the presently claimed formulations containing less than 0.1% DHA because to obtain such would require purifying EPA to substantially exclude DHA. Applicant respectfully asserts that present claims 47 and 65 are not anticipated by Horrobin, and are therefore in condition for allowance. Claims 49, 50, 52, 54-63 and 68 which depend from claims 47 or 65 are also therefore not anticipated and thus allowable. Accordingly, the applicants request the examiner withdraw the rejection.

Rejection of claims 47-50, 52, 57-62, 64, 65 and 68 under 35 U.S.C. 102(a)

The examiner has rejected claims 47-50, 52, 57-62, 64, 65 and 68 under 35 U.S.C. 102(a) as being anticipated by Tsuzuki et al. (Nutrition and Cancer 2004). For the same reasons stated above, applicant respectfully contends that Tsuzuki et al. cannot be said to anticipate the presently claimed formulations having less than 0.1% DHA. Again, there is no mention or suggestion in Tsuzuki to produce a purer EPA with substantially no DHA. Conversely, Tsuzuki teaches away from purifying associated DHA out of the disclosed EPA compositions, noting the antitumor effect of the presence of both DHA and EPA, as referred to below.

A purified form of a compound is patentable over an impure form. The purified form of a known mixture is only prima facie obvious if a person of ordinary skill in the art would have some reason to believe that the mixture derives properties from particular components (*Aventis Pharma & King Pharma v. Lupin Ltd.* (Fed. Cir. 2007)). The purified compound is not prima facie obvious over the mixture, even without an explicit teaching that the ingredient should be concentrated or purified, if the prior art teaches away from the use of the pure form rather than the mixture (*ibid.*).

Nowhere in the prior art is any benefit taught or suggested concerning purifying EPA so as to substantially exclude DHA. Applicant contends that the prior art teaches away from the idea that benefits are to be gained by excluding DHA. In a contemporaneous patent document, Horrobin disclosed the benefits of treating schizophrenia and related disorders with DHA as well as with EPA (see EP 0347056 at page 5 at lines 12-14, and at page 7 at lines 27-28, attached).

Tsuzuki, cited by the examiner, also states DHA's (with EPA's) role in strong and selective apoptosis in cultured human tumor cells.

Applicant respectfully asserts that present claims 47 and 65 are not anticipated by Tsuzuki, and are therefore in condition for allowance. Claims 49, 50, 52, 57-62 and 68 which depend from claims 47 or 65 are also therefore not anticipated and are thus allowable. Accordingly, the applicants request the examiner withdraw the rejection.

Applicant believes the claims are allowable and requests reconsideration. The examiner is invited to call the undersigned attorney if it is believed that such a communication will expedite grant of the case.

In view of the foregoing, the Applicants submit that all claims are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. The fee for a RCE is included herewith. In the event that there are any fees dues and owing in connection with this matter, please charge the same to our Deposit Account No. 11-0223.

Respectfully submitted,

Dated: April 7, 2009

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